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⑤④ **Ventricular assist device and method of manufacture.**

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Description

1. Field of the Invention

This invention relates to an artificial heart apparatus, and more particularly, to ventricular assist devices and a method of manufacturing the ventricular assist devices.

2. The Prior Art

Clinical experience has shown that the cardiovascular circulation of patients in severe or even total heart failure can be sustained with proper left ventricular and right ventricular assist devices (hereinafter "LVAD" and "RVAD", respectively). However, when a heart is in severe left ventricular failure and needs support for the left ventricle, there is a good chance that the right ventricle will begin to fail when it has to cope with the increased return from the left ventricle plus the return from the LVAD. A common experience then is that less and less blood returns from the lungs to the left atrium, and the LVAD's and the patient's cardiac output decrease. Only a few people recover after support to the left ventricle. And, when patients are finally weaned off the LVAD, the long term results are still very disappointing. Of the few patients in the world literature who initially survived, most have died after a few weeks or months. This experience leads to the conclusion that for serious cases of heart failure, one should aim for long term support rather than support limited to hours, days, or weeks. Further, one should be prepared not to just support the left ventricle, but both ventricles. However, presently there are no LVADs and RVADs that fit easily and properly inside the human chest. Typically LVADs have to be used either in the abdominal cavity or outside the chest. Also, as a rule total artificial hearts fit less than ideally inside the chest. Moreover, production methods for artificial hearts or heart assist devices presently in use are time consuming, cumbersome and unduly expensive. Thus, what is needed in the art are ventricular assist devices which overcome the disadvantages that have been experienced with the prior art type devices.

US-A-4152785 discloses an artificial heart contained within a rigid housing whose dimensions and shape are close to those of a natural heart which is intended to replace completely a natural heart. The device has an article chamber within surrounded by the ventricle chambers.

This device, being of the size and shape of a natural heart, and being rigid, may not be installed alongside the natural heart or under the skin as a ventricular assist device. Furthermore its configuration prevents the use of echocardiograph since interferences due to the working fluid are present.

Brief Summary of the Invention

According to the present invention there is provided a ventricular assist device in accordance with the appended claims.

The apparatus and method of the present invention consist of a novel ventricular assist device and

its method of manufacture. The device includes a housing that contains within it an atrial compliance membrane and a ventricular pumping membrane. The membranes and housing are specially constructed to eliminate seams, ridges and places where thrombi could form. The atrial compliance membrane may be formed with an integral extension that serves as a monocusp mitral valve. The ventricular assist device of the present invention may be constructed and used as either an LVAD or as an RVAD or, when both an LVAD and RVAD are used in combination, as a total artificial heart. The ventricular assist device is shaped in such a fashion that it can be conveniently placed and used outside the chest, against the skin, under the skin, inside the chest but exterior to the pleura, or inside the pleura. The ventricular assist device of the present invention may be shielded by an artificial pericardium and is designed so that it will interfere minimally with pulmonary function. Additionally, the ventricular assist device of the present invention may be constructed using a novel vacuum molding process that is simple, fast, and inexpensive.

Another advantage of the present invention is that it can provide a ventricular assist device wherein the mitral valving mechanism may be formed as an integral extension of the atrial compliance membrane.

Furthermore, the ventricular assist device is designed so that when implanted under the skin or inside the chest of a patient, the blood containing ventricular pumping chamber and the artificial atrium of the device will be oriented towards the outside of the patient so that echocardiography can be conveniently used to visualize movements of the membranes and the valves to assess their function and to detect the presence of any thrombi.

These and other objects and features of the present invention will become more fully apparent from the following description and appended claims taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

Figure 1 is a perspective illustration of one presently preferred embodiment of the ventricular assist device of the present invention configured as an LVAD.

Figures 2 and 3 schematically illustrate the placement of an LVAD and RVAD in the chest of a patient.

Figure 4 is an exploded perspective illustration of the embodiment of Figure 1.

Figure 5A is a longitudinal cross-sectional view taken along line 5—5 of Figure 1, and illustrates the position of the ventricular pumping membrane and atrial compliance membrane during the systolic phase of the device.

Figure 5B is a longitudinal cross-sectional view taken along line 5—5 of Figure 1, and illustrates the ventricular pumping membrane and atrial compliance membrane during the diastolic phase of the device's operation.

Figure 6A is a cross-sectional view taken along

line 6—6 of Figure 1, and illustrates the ventricular pumping membrane and arterial valve mechanism during the systolic phase of the device's operation.

Figure 6B is a cross-sectional view taken along line 6—6 of Figure 1, and illustrates the arterial valve mechanism and ventricular pumping membrane during the diastolic phase of the device's operation.

Figures 7 through 14 schematically illustrate one presently preferred method of manufacturing an artificial ventricle in accordance with the method of present invention.

Detailed Description of the Preferred Embodiments

Reference is next made to the drawings wherein like parts are designated with like numerals throughout.

1. The Apparatus

One presently preferred embodiment of the ventricular assist device of the present invention is generally indicated at 10 in Figure 1. The ventricular assist device illustrated in Figure 1 is configured as an LVAD although it will of course be appreciated that the ventricular assist device of this invention can be used either as an LVAD or an RVAD, or in combination as a total artificial heart.

When used to assist the natural heart (not shown), the LVAD 10a and RVAD 10b (see Fig. 2) are connected to the natural heart via tubes 11 and 13. On the left side, blood is sucked from the left ventricle or from the left atrium possibly, but not necessarily, via the superior pulmonary vein (not shown) and through the tube 11a. The blood is returned from LVAD 10a through tube 13a to the ascending aorta (not shown). On the right side, the blood may be taken from the right atrium only, or, if desired, also from the right ventricle through tube 11b. Blood is returned from RVAD 10b through tube 13b to the pulmonary artery. Thus, LVAD 10a controls or assists systemic circulation, while RVAD 10b controls or assists pulmonary circulation.

With further reference to Figures 1 through 3, it will be seen that the ventricular assist device of this invention has an exterior shape that is gently curved and which is generally flat. Thus, unlike the prior art type ventricular assist devices or total artificial hearts currently in use, the ventricular assist device of the present invention can be conveniently implanted under the skin, inside the chest but exterior to the pleura, or inside the pleura. The unique size and flat, contoured shape of the ventricular assist device 10 avoids crowding of adjacent organs and accommodates implantation within the available anatomical space as generally illustrated in Figures 2 and 3. This is a significant advantage since it makes the ventricular assist device much more comfortable and convenient, and thus enhances the ability of the device to be used for purposes of providing long-term support. In contrast, the prior art type devices are much larger and must typically be

worn outside of the patient or inside the abdominal cavity.

With further reference to Figure 1, the ventricular assist device 10 includes a housing generally designated 12. Housing 12 includes an inlet port 14 through which blood is admitted into the housing and an outlet port 16 through which the blood is expelled as it is pumped. Housing 12 also includes a port 18 through which a driving fluid is pumped into and out of the ventricular pumping chamber as hereinafter more fully described. Port 18 is connected through tubing (not shown) to a conventional pump (not shown), while ports 14 and 16 are connected through tubing to the appropriate arteries, atria or veins of the patient as described above.

As best shown in Figure 4, housing 12 is formed in three parts which include the blood side of the housing indicated at 20, an atrium cover indicated at 22 and a ventricle cover indicated at 24. The interior surface 30 of the blood side 20 of housing 12 is constructed so that it is gently curved and presents a smooth surface. Additionally, the internal seams formed at the junctures between the pumping membrane 28, the atrial compliance membrane 26 and blood side portion 20 of housing 12 may be rendered smooth and essentially seamless by applying a solution containing a suitable elastomer such as polyurethane to each of the seams. This can be done by applying the solution to the inner seam through a syringe with a long cannula, or by covering the entire intima with an air-dried surface of polyurethane by using a rotational cavity molding process. Advantageously, this helps to prevent the formation of thrombi as blood flows into and is pumped out of the housing.

The blood side 20 of housing 12 is shaped so as to provide an elongated atrial blood chamber 32 which communicates with a generally circular shaped ventricular blood chamber 34. The atrial and ventricular blood chambers 32 and 34 formed in the blood side portion 20 of housing 12 are separated by a slight ridge 33 (see also Figs. 5A and 5B).

A compliance membrane 26 is sealed between the atrium cover 22 and the blood side portion 20 of housing 12 which forms the atrial blood chamber 32. As hereinafter more fully described, the edge 38 of compliance membrane 26 is vacuum formed such that it is folded over and is bonded to the corresponding edge 40 (see also Figs. 5A and 5B) of the atrium cover 22.

A one-way flap valve 36 is formed as an integral extension of the atrial compliance membrane 26. Flap valve 36 functions as a monocusp mitral valve which controls the flow of blood from the atrial blood chamber 32 (see Figures 5A and 5B) to the ventricular blood chamber 34. The one-way flap valve 36 is bonded to the curved edge 44 of the atrium cover 22 along a corresponding portion 46 of the flap valve 36. Thus, a fluid tight seal is formed between the atrium cover 22 and blood side portion 20 of housing 12 at the periphery of the compliance membrane 26. In this manner the

atrial compliance chamber that is formed in the space 33 (see Figs. 5A and 5B) between the atrium cover 22 and compliance membrane 26 is completely sealed and is fluid tight with respect to the atrial blood chamber that is formed in the space 32 between the compliance membrane 26 and blood side portion 20 of housing 12.

In like fashion, a ventricular pumping membrane 28 is sealed between the ventricle cover 24 and blood side portion 20 of housing 12 that forms the ventricular blood chamber 34. The ventricular pumping membrane 28 is also vacuum formed such that its edge 48 folds over and is bonded to the corresponding edge 50 of the ventricle cover 24. As best illustrated in Figures 5A and 5B, a portion of the edge 48 of ventricular pumping membrane 28 is also bonded between the ventricle cover 24 and atrium cover 22. Thus, the ventricular pumping membrane 28 provides a fluid tight seal at its periphery which separates the drive fluid pumping chamber 35 (see Figs. 5A—6B) formed between the ventricle cover 24 and ventricular pumping membrane 28 from the ventricular blood chamber 34 that is formed between the ventricular pumping membrane 28 and blood side portion 20 of housing 12.

As illustrated in the enlarged insert of Figure 5B, the ventricular pumping membrane 28 may be constructed as a double layer pumping membrane which includes two layers of elastomers 60 and 62 separated by a lubricant layer 64. The elastomers may be polyurethane, polyethylene or other similar kinds of blood compatible elastomers, while the lubricant may be graphite. The graphite layer 64 permits the elastomeric layers 60 and 62 to slide freely relative to each other. This multi-layered configuration of pumping membrane 28 provides greatly increased durability and safety, while preserving the necessary flexibility. Other, additional layers of elastomeric material could also be provided, and the compliance membrane 26 may also be constructed as a multilayered membrane if desired.

A plurality of divergent fluid channels 58 (see Fig. 4) are formed on the interior surface of the ventricle cover 24. The divergent fluid channels 58 fan outwardly from the port 18 to provide a distribution system for evenly dispersing the drive fluid admitted through the port 18 into the ventricular pumping chamber 35. As hereinafter more fully described, as the drive fluid is alternately pumped into the ventricular blood chamber 35 and then withdrawn, the membrane 28 will expand and then retract, causing the blood to be pumped from the ventricular blood chamber 34.

As shown in Figures 6A and 6B, blood pumped from the ventricular blood chamber 34 is controlled by an arterial valve mechanism positioned in the outlet port 16. The arterial valve mechanism is a conventional heart valve which consists of a small disc 66 supported between two offset bars 68 and 70. The disc 66 is normally in a closed position (see Fig. 6B) while blood fills the ventricular blood chamber 34 during diastole, and is

changed to the open position (see Fig. 6A) as blood is pumped through the outlet port 16 during systole. The arterial valve mechanism may be separately constructed so that it can be attached to the device at the time of surgical implantation, in accordance with well-known surgical techniques.

With continued reference to Figure 4, a thin, flacid membrane 52 is provided which corresponds in its general size and shape to the upper portion of the housing 12 formed by the ventricle cover 24 and atrium cover 22. The membrane 52 is provided with a hole 54 at one end which fits over the port 18 of ventricle cover 24. The membrane 52 is bonded along the edge 42 of the blood side portion 20 of housing 12 so as to form a fluid tight seal. Membrane 52 serves as an artificial pericardium that encloses gaseous fluid which is alternately admitted and expelled from the atrial compliance chamber 33 (see Fig. 5B) through the hole 56 provided in the atrium cover 22. When an LVAD and RVAD are used together (see Fig. 2) the cavities of the artificial pericardium of each device may be interconnected to provide a larger compliance volume and to take advantage of alternate pulsation of the LVAD and RVAD, which greatly reduces the need of such volume. The artificial pericardium formed by membrane 52 also provides a smooth outer surface which fits comfortably under the skin or inside the chest of a patient.

The artificial pericardium formed by membrane 52, as well as the ventricle cover 24, atrium cover 22, blood side portion 20 of housing 12 and membranes 26 and 28 may be formed from biocompatible elastomers, in accordance with the method hereinafter more fully described. The inside surfaces of the ventricular assist device which come into contact with blood can be coated with a biolized layer consisting of porous polyurethane filled for example with cross-linked gelatin, or they may be treated with Heparin, prostaglandin or other anticoagulants. The outside surfaces of the device 10 can be coated with antibiotics such as Gentamycin.

The operation of the ventricular-assist device of the present invention is best understood with reference to Figures 5A—6B. With reference first to Figure 5A, as schematically represented by the arrow 72, blood enters the ventricular-assist device through the inlet port 14 and begins to fill the atrial blood chamber 32. As the atrial blood chamber 32 is filled with blood, the atrial compliance membrane 26 expands, forcing the gaseous fluid contained in the atrial compliance chamber 33 out of the atrial compliance chamber 33 through the holes 56 contained in the atrium cover 22. The gaseous fluid from the atrial compliance chamber 33 fills the space 51 that is enclosed by the thin, flacid membrane 52 causing the membrane 52 to expand.

At the same time as blood is filling the atrial blood chamber 32, a drive fluid, which may be either gaseous or liquid, is pumped into the ventricular pumping chamber 35 causing the ventricular pumping membrane 28 to expand and

expel the blood that is contained in the ventricular blood chamber 34 through the outlet port 16 and arterial valve mechanism 66 (see also Fig. 6A). As the ventricular pumping membrane 28 expands and expels the blood from the ventricular blood chamber 34, the pressure exerted on the blood contained in the ventricular blood chamber 34 maintains the one-way flap valve 36 of the atrial compliance membrane 26 in the closed position, as illustrated in Figure 5A. This sequence of the device's operation is referred to as the systolic phase of the device's operation since blood is expelled from the ventricular-assist device by the pumping membrane 28 during this portion of the device's operation.

The second or diastolic phase of the device's operation is illustrated in Figures 5B and 6B. As shown in those figures, after blood has been expelled from the ventricular blood chamber 34, the drive fluid is withdrawn by the pumping mechanism (not shown) through the port 18. As the drive fluid is withdrawn through port 18, the ventricular pumping membrane 28 is pulled upwardly. This releases the fluidic pressure holding the one-way flap valve 36 in the closed position so that the valve 36 may then be opened as illustrated in Figure 5B. As the one-way flap valve 36 is opened, blood flows from the atrial blood chamber 32 past the one-way flap valve 36 and into the ventricular blood chamber 34, as schematically illustrated by the arrow 74. As the blood flows from the atrial blood chamber 32 and fills the ventricular blood chamber 34, the gaseous fluid contained in the space 51 flows through the ports 56 of atrium cover 22 and fills the atrial compliance chamber 33. The disc 66 of the atrial valve mechanism (Fig. 6B) remains closed until the ventricular blood chamber 34 is completely filled with blood at which time the systolic phase begins again and the drive fluid is then pumped back into the ventricular pumping chamber 35 causing the pumping membrane 28 to expel the blood in the manner previously described.

Advantageously, as shown in Figure 5A, the one-way flap valve 36 is formed as an integral extension of the atrial compliance membrane 26. Flap valve 36 also is gently curved so that it conforms to the contour of ventricular blood chamber 34. Thus, during the systolic phase of the device's operation, the ventricular side of the flap valve 36 is continually washed by the motion of the blood within the ventricular blood chamber 34. This helps to prevent the formation of thrombi in and around the valve 36.

A further significant advantage of the ventricular-assist device of the present invention is that the ventricular blood chamber 34 and atrial blood chamber 32 are located on the same side of the housing. Thus, when the device is placed in a patient such as illustrated in Figures 2 and 3, the blood side portion 20 of the housing 12 faces outwardly. And since the ventricular pumping chamber 35 and atrial compliance chamber 33 are located on the opposite side of the housing and are oriented so that they face inwardly with

respect to the patient, neither the ventricular pumping chamber 35 nor the atrial compliance chamber 33 will interfere with ultrasound waves passing through the blood side portion 20 of the device when using echocardiography to take pictures of the device after it has been implanted.

2. The Method of Manufacture

The ventricular assist device of the present invention may be constructed using a novel vacuum-molding process that is simple, fast and inexpensive. By way of background, vacuum-molding involves a process in which a sheet or layer of thermoplastic polymer or elastomer material is heated until it becomes very soft and malleable. The soft layer of thermoplastic is then lowered over a mold and a vacuum is created under the mold which sucks the elastomer tightly over the top of the mold. In this way, the thermoplastic material is formed by the mold. Mechanical help, for example by pressing the top of the vacuum-formed thermoplastic layer with a wooden form, may be used to smooth the vacuum-formed layer of thermoplastic and this is sometimes advantageous.

Using this technique, a vacuum formed print made over a convex mold will have an exact inner dimension. A vacuum formed print made over a concave mold will have an exact outer dimension. Thus, one can predict an exact fit between the prints vacuum formed over convex and concave molds when the molds themselves are fitted, which can easily be done by casting one mold inside the other.

The general principles described above may be used in connection with one presently preferred method of the present invention, as schematically illustrated in Figures 7—14. For purposes of simplifying the drawing and description, Figures 7—14 schematically represent the steps for manufacturing an artificial ventricle, including a ventricular blood chamber and a drive fluid pumping chamber that are separated by a ventricular pumping membrane sealed within a housing, as hereinafter more fully described. It will of course be appreciated that the same general technique used to construct the artificial ventricle of Figure 14 may also be employed to construct a complete LVAD or RVAD in accordance with the embodiment of the present invention illustrated in Figure 4, as hereinafter described.

As illustrated in Figures 7 and 8, a convex mold 76 is first prepared having the desired shape of the artificial ventricle. The convex mold 76 is supported on a pedestal 82 to insure that the vacuum formed thermoplastic will cover the greatest circumference of the mold 76. A thin layer of thermoplastic polymer or elastomer 84a is supported at its ends as at 86 and is suspended over the top of the mold 76. A source of heat 88 is then energized so that the layer 84a of thermoplastic becomes soft and malleable. As schematically represented by the arrows 90, a vacuum is then applied beneath the mold 76 so that the layer 84a of thermoplastic is sucked down onto the top of

the mold as illustrated best in Figure 8. After the layer 84a of thermoplastic cools, it is cut at the line indicated at 89. Layer 84a forms one of the thin layers of the double layer ventricular pumping membrane, as more fully described below.

The steps of the process illustrated in Figures 7 and 8 are repeated so that an extra layer of polyethylene 84c of the same thickness as layer 84a is vacuum formed over the convex mold 76 and layer 84a. Layer 84c, which will later be removed, simulates the thickness of that part of pumping membrane 84b (see Fig. 11) that will attach to the concave drive chamber 85b. From the convex mold 76, a concave mold 78 is formed which corresponds to the thickness of the convex mold 76, including the thin layers 84a and 84c of polyethylene. Mold 78 is provided with a small bore 80 which eliminates entrapment of air when the thermoplastic is vacuum formed over the concave mold 78.

Next, as shown in Figure 9, layer 84c is removed and the mold 76 is turned over. A somewhat thicker layer 85 of thermoplastic is then heated and vacuum formed over molds 76 and 78. The layer 85 of thermoplastic is then cut (see Figure 10) at the lines indicated at 89 and 91. The portion 85a thermoplastic vacuum formed over mold 76 and the portion 85b of thermoplastic vacuum formed over mold 78 form the ventricular blood chamber and drive fluid pumping chamber portions of the housing or shell of the artificial ventricle. The portion 85a of the artificial ventricle vacuum formed over convex mold 76 will have an outer dimension that will exactly fit the inner dimension of the portion 85b of the artificial ventricle vacuum formed over the concave mold 78 even when the portion 84b (see Fig. 11) of the pumping membrane is in place, due to the extra layer 84c of polyethylene that is removed.

As shown in Figures 11 and 12, a second thin layer 84b of thermoplastic is next vacuum formed directly onto the layer 85b. Layer 84b forms the other thin layer of the double pumping membrane. It will of course be appreciated that layers 84a and 84b may be different types of polymers if desired.

The thin layer of thermoplastic 84a vacuum formed over convex mold 76 is bonded around its periphery as at 95 (see Fig. 10) to the inside surface of the layer of thermoplastic 85a. Similarly, the thin layer of thermoplastic 84b vacuum formed over the concave mold 78 (see Fig. 12) is bonded around its periphery at 93 to the outer surface of the edge of the layer 85b. The bonding may be achieved by using a glue, a solvent, by heat sealing, or by ultrasonic welding. The thin layer of thermoplastic 84a vacuum formed over the convex mold 76 forms the blood side of the double pumping membrane and the thin layer 84b vacuum formed over the concave mold 78 forms the drive fluid or air side of the double pumping membrane.

After the layer of thermoplastic 84b is cut along line 89 (see Fig. 12) the drive fluid pump-

ing chamber portion of the artificial ventricle formed by the layers 85b and 84b is removed from the concave mold 78 and is placed on top of the ventricular blood chamber portion of the artificial ventricle vacuum-formed over the convex mold 76, as illustrated in Figure 13. The two portions of the artificial ventricle are brought together such that the thin layers of thermoplastics 84a and 84b are assembled together to form a double layer pumping membrane. The two layers of thermoplastic 84a and 84b may be separated by a layer of lubricant such as graphite.

Another, thicker layer 87 of thermoplastic polymer is then suspended over the top of the two portions of the artificial ventricle assembled together and is heated and vacuum formed over the top of the assembly. The layer 87 of thermoplastic is then cut and bonded at 97 (see Fig. 14) to the periphery of thermoplastic layer 85a so as to form a completely enclosed artificial ventricle which includes a ventricular blood chamber and a drive fluid pumping chamber separated by a double layer pumping membrane. The double layer pumping membrane is formed by the two relatively thin layers of thermoplastic 84a and 84b which are separated by a graphite or other lubricant. The housing of the artificial ventricle is formed by the layers 85a and 85b which are in turn joined together by the outer layer 87 of thermoplastic.

The mold 76 is constructed from a material that can be easily melted, dissolved or broken to permit removal of the mold through the inlet and outlet ports (not shown) of the artificial ventricle after it has been completely formed. Such materials include certain silicones, Wood's metal, wax, polyethylene or ice. Once the mold 76 has been melted, dissolved or broken and removed through the inlet or outlet ports of the artificial ventricle, the inner seams within the ventricular blood chamber can be essentially eliminated by applying a solution containing polyurethane through a long, thin cannula attached to a syringe. The cannula may be inserted through either the inlet or the outlet port (not shown) of the artificial ventricle similar to the manner described above in connection with Figure 4. In the alternative, the entire intima of the ventricular blood chamber may be covered with an air-dried surface of polyurethane using a rotational cavity molding process.

In accordance with the general principles schematically illustrated in connection with Figures 7-14, the embodiment of the ventricular assist device of the present invention illustrated in Figure 4 can be simply and economically manufactured. Convex molds are first prepared having the shape of the housing 12 which is defined by the blood side portion 20 of the housing, the ventricle cover 24 and atrium cover 22. Using the convex molds prepared for each of these parts, a first layer of thermoplastic polymer is vacuum formed over the convex molds in the manner previously described. The first layer of

thermoplastic is then cut to form the blood side portion 20, atrium cover 22 and ventricle cover 24 of the housing 12.

Using the convex molds that were used to form the ventricle cover 24 and atrium cover 22, concave molds are formed corresponding to each of the convex molds. A thin layer of thermoplastic polymer is then vacuum formed over the concave molds to form the first layer of the ventricular pumping membrane 28 and atrial compliance membrane 26. This layer of thermoplastic is then coated with a lubricant such as graphite, except at its peripheral edges. A second thin layer of thermoplastic is vacuum formed over the convex mold and is bonded at its periphery to the first layer in order to form a double layer pumping membrane such as previously described in connection with Figure 5B. It will, of course, be appreciated that additional layers may be formed over any convex mold if it is desired to have more than two layers for the ventricular pumping membrane 28 or atrial compliance membrane 26.

When the atrial compliance membrane 26 and ventricular pumping membrane 28 are cut and removed from the concave molds, each of the membranes 28 and 26 will have a peripheral edge 48 and 38, respectively, that is folded over and which may be bonded to the peripheral edge 50 and 40 of the ventricle cover 24 and atrium cover 22.

Rather than using the concave molds, the membranes 26 and 28 may be vacuum formed directly onto the atrium cover 22 and ventricle cover 24. For example, to vacuum form the ventricular pumping membrane 28 directly onto the ventricle cover 24, the ventricle cover 24 is turned over and is supported on a pedestal so that the peripheral edge 50 of the ventricle cover 24 extends slightly beyond the edge of the supporting pedestal. The first thin layer of thermoplastic polymer is then vacuum formed directly onto the concave interior surface of the ventricle cover 24. The first thin layer of thermoplastic is then coated with graphite lubricant as described above. The periphery of the ventricular pumping membrane 28 will be vacuum formed over the edge 50 of the ventricle cover 24 and may be bonded thereto form a fluid tight seal about the entire periphery of the ventricle cover 24. If a double layer pumping membrane is desired, the second thin layer of thermoplastic may be vacuum formed over a corresponding convex mold.

In like manner, the atrium cover 22 may be turned over and supported on a pedestal such that the edges 40 and 44 of the atrium cover will be slightly exposed and the layer of thermoplastic used to form the atrial compliance membrane 26 may then be vacuum formed directly onto the concave interior surface of the atrium cover 22.

Once the blood side portion 20, atrium cover 22 and ventricle cover 24 of the housing and the membranes 26 and 28 have each been vacuum formed, assembled and bonded at the periphery to form a fluid tight ventricular assist device, the

thin flaccid membrane 52 may then be vacuum-formed over the ventricle cover 24 and atrium cover 22 to form the artificial pericardium of the device.

As previously indicated, interior seams formed along the peripheral edges of the membranes 26 and 28 can be smoothed by applying a polyurethane in solution to the seams through a long thin cannula introduced through any of the ports 14 or 16. In the alternative, the entire intima or interior surface of the atrial and ventricular blood chambers can be coated with an air-dried surface of polyurethane using a rotational cavity molding process, as is well-known in the art.

It will be appreciated that the thickness of the layers of thermoplastic polymer used for the housing 12 and the membranes 26 and 28 are a matter of design choice. It is desirable that the housing 12 be thick enough to adequately protect the membranes 26 and 28 from puncture or damage, whereas the membranes 26 and 28 must be more thin so that they can be easily flexed for purposes of the operation of the device as it pumps blood.

Claims

1. Ventricular assist device comprising:

an elongate flexible housing (12) that is generally flat in shape and gently curved so that it may be comfortably implanted under the skin or inside the chest of a patient, said housing (12) having an inlet means (14) through which blood is admitted into said housing, an outlet means (16) through which blood is expelled from said housing,

a compliance membrane (26) disposed within said housing (12), said compliance membrane (26) dividing a first portion of the interior of said housing into an atrial blood chamber (32) and an atrial compliance chamber (33), said atrial blood chamber (32) being in fluid communication with said inlet means (14), and the housing having one or more openings (18) through which fluids may enter and leave said atrial compliance chamber (33); and

a pumping membrane (28) disposed within said housing, said pumping membrane (28) dividing a second portion of the interior of said housing into a ventricular blood chamber (34) and a driving fluid pumping chamber (35), said pumping membrane (28) being forceably displaceable by said driving fluid in order to expel blood from said ventricular blood pumping chamber through said outlet means, characterised by the pumping membrane (28) being oriented in generally the same plane as the compliance membrane (26) and said atrial (32) and ventricular (34) blood chambers being positioned at opposite longitudinal ends and on the same side of said housing (12).

2. A ventricular assist device as claimed in claim 1 wherein said compliance membrane (26) has as an integral part thereof a one way flap valve (36) formed on one end of said compliance membrane

for controlling the flow of blood out of said atrial blood chamber.

3. A device as claimed in either of claims 1 or 2 comprising one way valve means (66) positioned at said outlet means (16) for controlling the flow of blood expelled from said ventricular blood chamber by said pumping means.

4. A device as defined in any of claims 1 to 3 wherein the interior surfaces of said atrial blood chamber (32) and said ventricular blood (34) chamber are essentially smooth and seamless, and are gradually curved so as to minimise the formation of thrombi as blood flows there-through.

5. A device as defined in any of claims 2 to 4 wherein said flap (36) is configured to conform to the contour of said ventricular blood chamber (34) when said flap is closed to prevent reverse flow of blood into said atrial blood chamber (32).

6. A device as defined in any of claims 3 to 5 wherein the one-way valve (66) positioned at said outlet means (16) is detachable therefrom.

7. A device as defined in any of claims 1 to 6, further comprising a plurality of fluid channels (58) formed in the interior surface of said housing (12) for dispersing said drive fluid underneath said pumping membrane (28).

8. A device as defined in any of claims 1 to 7, wherein said compliance membrane (26) and said pumping membrane (28) comprise a plurality of layers made from elastomers.

9. A device as defined in claim 8, wherein said layers are bonded together only at the periphery of said membranes.

10. A device as defined in claim 8 or 9, wherein each said layer is a different type of elastomer and wherein each said layer is separated by a lubricant.

11. A device as defined in claims 1 to 10, further comprising a thin, flaccid membrane (52) in the form of an artificial pericardium bonded to said housing so as to enclose said openings.

12. A device as defined in claims 1 to 11 further comprising a plurality of fluid channels (56) formed in the interior surface of said housing (12) for dispersing said drive fluid underneath said pumping membrane (28).

13. A method of manufacturing a ventricular assist device, the method comprising the steps of:

(a) vacuum forming a housing (12) having an inlet means (14) through which blood is communicated to said housing, an outlet means (16) through which blood is expelled from said housing, and means (18) through which a drive fluid is pumped into and out said housing;

(b) vacuum forming a compliance membrane (26) that includes an integral one-way flap valve (36) for controlling the flow of blood through said housing;

(c) vacuum forming a pumping membrane (28);

(d) sealing the compliance membrane (26) within a first portion of said housing so as to form an atrial blood chamber (32) and an atrial compliance chamber (33), that are separated by a fluid

tight seal at the periphery of said compliance membrane (26); and

(e) sealing the pumping membrane (28) within a second portion of said housing so as to form a ventricular blood chamber (34) and a drive fluid pumping chamber (35) that are separated by a fluid tight seal at the periphery of said pumping membrane;

whereby the pumping membrane (28) is oriented in the same plane as the compliance membrane (26) and the atrial and ventricular blood chambers (32, 34) are positioned at opposite longitudinal ends and on the same side of the housing.

14. A method as defined in claim 13, wherein step (a) comprises the steps of:

(a1) preparing a convex mould having the same shape as the desired ventricular assist device;

(a2) vacuum forming a first layer of thermoplastic polymer over said mould;

(a3) turning the mould over; and

(a4) vacuum forming a second layer of thermoplastic polymer over said mould.

15. A method as defined in claim 13, wherein step (a) comprises the steps of:

(a1) preparing a convex mould having the same shape as the desired ventricular assist device;

(a2) preparing a concave mould cast from the bottom portion of said convex mould; and

(a3) vacuum forming a layer of thermoplastic polymer over the top portion of said convex mould and over the concave mould.

16. A method as defined in any of claims 13 to 15, wherein step (b) comprises the steps of:

(b1) preparing a mould having the same shape as the desired compliance membrane; and

(b2) vacuum forming a thin layer of thermoplastic polymer over said mould.

17. A method as defined in claim 16, wherein step (b) further comprises the steps of:

(b3) treating the convex surface of the layer vacuum formed in step (b2) with a lubricant;

(b4) repeating steps (b2) and (b3) several times to form a multi-layer compliance membrane; and

(b5) bonding the several layers together at the edges thereof.

18. A method as defined in any of claims 13 to 17, wherein step (c) comprises the steps of:

(c1) preparing a convex mould having the same shape as the desired pumping membranes; and

(c2) vacuum forming a thin layer of thermoplastic polymer over said mould.

19. A method as defined in claim 18, wherein step (c) further comprises the steps of:

(c3) treating the convex surface of the layer vacuum formed in step (c2) with a lubricant;

(c4) repeating steps (c2) and (c3) several times to form a multi-layer pumping membrane; and

(c5) bonding the several layers together at the edges thereof.

20. A method as defined in any of claims 13 to 17, wherein step (c) comprises the steps of:

(c1) treating the edges of thermoplastic layer vacuum formed on to said concave mould with an adhesive bonding agent; and

(c2) vacuum forming a thin layer of thermoplastic polymer on to the thermoplastic layer of step (c1).

Patentansprüche

1. Ventrikuläre Hilfsvorrichtung umfassend:

ein längliches, flexibles Gehäuse (12), das im allgemeinen flach und leicht gebogen ist, so daß es bequem unter die Haut oder in den Brustkorb eines Patienten implantiert werden kann, wobei das Gehäuse (12) eine Einlaßeinrichtung (14), durch die das Blut in das Gehäuse eingelassen wird, und eine Auslaßeinrichtung (16), durch die das Blut aus dem Gehäuse ausgestoßen wird, aufweist;

eine nachgiebige Membran (26), die in dem Gehäuse (12) angeordnet ist, wobei die nachgiebige Membran (26) einen ersten Teil des Gehäuseinneren in eine Atriumblutkammer (32) und in eine nachgiebige Vorhofkammer (33) aufteilt, wobei die Atriumblutkammer (32) mit der Einlaßeinrichtung (14) in Strömungsmittelverbindung ist und das Gehäuse eine oder mehrere Öffnungen (18) aufweist, durch die Strömungsmittel in die nachgiebige Vorhofkammer (33) eintreten und diese verlassen können; und

eine in dem Gehäuse angeordnete pumpende Membran (28), die einen zweiten Teil des Gehäuseinneren in eine ventrikuläre Blutkammer (34) und eine Antriebsströmungsmittel pumpende Kammer (35) aufteilt, wobei die pumpende Membran (28) durch das Antriebsströmungsmittel zwangsweise auslenkbar ist, um das Blut aus der ventrikulären Blutpumpkammer durch die Auslaßeinrichtung auszustoßen,

dadurch gekennzeichnet, daß die pumpende Membran (28) im wesentlichen in der gleichen Ebene wie die nachgiebige Membran (26) orientiert ist, und daß die Atriumblutkammer (32) und die ventrikuläre Blutkammer (34) an in Längsrichtung entgegengesetzten Enden und auf der selben Seite des Gehäuses (12) positioniert sind.

2. Ventrikuläre Hilfsvorrichtung nach Anspruch 1, wobei die nachgiebige Membran (26) als integrierter Teil derselben ein Einweg-Klappenventil (36) aufweist, das an einem Ende der nachgiebigen Membran ausgebildet ist, um den Blutfluß aus der Vorhofblutkammer zu steuern.

3. Vorrichtung nach Anspruch 1 oder 2, umfassend eine an der Auslaßeinrichtung (16) liegende Einwegventileinrichtung (66), um die Strömung des Blutes zu steuern, das aus der ventrikulären Blutkammer von der Pumpeinrichtung ausgestoßen wird.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, wobei die inneren Oberflächen der Atriumblutkammer (32) und der ventrikulären Blutkammer (34) im wesentlichen glatt und nahtlos sowie leicht gebogen sind, um die Entstehung von Thromben während des Blutflusses durch diese (Kammern) auf ein Minimum zu beschränken.

5. Vorrichtung nach einem der Ansprüche 2 bis 4, wobei die Klappe (36) derart geformt ist, daß sie sich in geschlossenem Zustand an die Kontur

der ventrikulären Blutkammer (34) anpaßt, um den Rückfluß von Blut in die Atriumblutkammer (32) zu verhindern.

6. Vorrichtung nach einem der Ansprüche 3 bis 5, wobei das an der Auslaßeinrichtung (16) gelegene Einwegventil (66) von dieser abnehmbar ist.

7. Vorrichtung nach einem der Ansprüche 1 bis 6, ferner umfassend mehrere Strömungsmittelkanäle (58), die in der inneren Oberfläche des Gehäuses (12) ausgebildet sind, um das Antriebsströmungsmittel unterhalb der pumpenden Membran (28) zu verteilen.

8. Vorrichtung nach einem der Ansprüche 1 bis 7, wobei die nachgiebige Membran (26) und die pumpende Membran (28) mehrere aus Elastomeren hergestellte Schichten umfassen.

9. Vorrichtung nach Anspruch 8, wobei die Schichten nur an den Rändern der Membranen miteinander verbunden sind.

10. Vorrichtung nach Anspruch 8 oder 9, wobei jede der Schichten aus einer anderen Art von Elastomeren besteht und jede der Schichten durch ein Gleitmittel von der anderen getrennt ist.

11. Vorrichtung nach den Ansprüchen 1 bis 10, ferner umfassend eine dünne, schlaffe Membran (52) in Form eines künstlichen Herzbeutels, die an dem Gehäuse befestigt ist, um die Öffnungen zu umschließen.

12. Vorrichtung nach den Ansprüchen 1 bis 11, ferner umfassend mehrere Strömungsmittelkanäle (56), die in der inneren Oberfläche des Gehäuses ausgebildet sind, um das Antriebsströmungsmittel unterhalb der pumpenden Membran (28) zu verteilen.

13. Verfahren zur Herstellung einer ventrikulären Hilfsvorrichtung, das folgende Schritte umfaßt:

(a) Vakuumformung eines Gehäuses (12) mit einer Einlaßeinrichtung (14), durch die Blut dem Gehäuse zugeführt wird, einer Auslaßeinrichtung (16), durch die Blut aus dem Gehäuse ausgestoßen wird, und einer Einrichtung (18), durch die ein Antriebsströmungsmittel in das Gehäuse hinein- und aus diesem herausgepumpt wird;

(b) Vakuumformung einer nachgiebigen Membran (26) mit einem integrierten Einweg-Klappenventil (36), um den Blutfluß durch das Gehäuse zu steuern;

(c) Vakuumformung einer pumpenden Membran (28);

(d) Versiegeln der nachgiebigen Membran (26) in einem ersten Teil des Gehäuses zur Bildung einer Atriumblutkammer (32) und einer nachgiebigen Vorhofkammer (33), die durch eine am Rand der nachgiebigen Membran (26) liegende strömungsmitteldichte Dichtung getrennt sind; und

(e) Versiegeln der pumpenden Membran (28) in einem zweiten Teil des Gehäuses zur Bildung einer ventrikulären Blutkammer (34) und einer ein Antriebsströmungsmittel pumpenden Kammer (35), die durch eine am Rand der pumpenden Membran liegende strömungsmitteldichte Dichtung getrennt sind;

wobei die pumpende Membran (28) in der

gleichen Ebene wie die nachgiebige Membran (26) orientiert ist, und die Atrium- und die ventrikuläre Blutkammer (32, 34) an in Längsrichtung entgegengesetzten Enden und auf der selben Seite des Gehäuses positioniert sind.

14. Verfahren nach Anspruch 13, wobei der Schritt (a) folgende Schritte umfaßt:

(a1) Herstellen einer konvexen Form, die die gleiche Gestalt wie die gewünschte ventrikuläre Hilfsvorrichtung hat;

(a2) Vakuumformung einer ersten Schicht aus thermoplastischen Polymeren über dieser Form;

(a3) Wenden dieser Form; und

(a4) Vakuumformung einer zweiten Schicht aus thermoplastischen Polymeren über dieser Form.

15. Verfahren nach Anspruch 13, wobei der Schritt (a) folgende Schritte umfaßt:

(a1) Herstellen einer konvexen Form, die die gleiche Gestalt wie die gewünschte ventrikuläre Hilfsvorrichtung hat;

(a2) Herstellen einer konkaven, aus dem unteren Teil der konvexen Form gegossenen Form; und

(a3) Vakuumformung einer Schicht aus thermoplastischen Polymeren über dem oberen Teil dieser konvexen Form und über der konkaven Form.

16. Verfahren nach einem der Ansprüche 13 bis 15, wobei der Schritt (b) folgende Schritte umfaßt:

(b1) Herstellen einer Form, die die gleiche Gestalt wie die gewünschte nachgiebige Membran hat; und

(b2) Vakuumformung einer dünnen Schicht aus thermoplastischen Polymeren über dieser Form.

17. Verfahren nach Anspruch 16, wobei der Schritt (b) ferner folgende Schritte umfaßt:

(b3) Behandlung der konvexen Oberfläche der in Schritt (b2) vakuumgeformten Schicht mit einem Gleitmittel;

(b4) Mehrfaches Wiederholen der Schritte (b2) und (b3) zur Bildung einer mehrschichtigen nachgiebigen Membran; und

(b5) Verbinden der verschiedenen Schichten an ihren Rändern.

18. Verfahren nach einem der Ansprüche 13 bis 17, wobei der Schritt (c) folgende Schritte umfaßt:

(c1) Herstellen einer konvexen Form, die die gleiche Gestalt wie die gewünschten pumpenden Membranen hat; und

(c2) Vakuumformung einer dünnen Schicht aus thermoplastischen Polymeren über dieser Form.

19. Verfahren nach Anspruch 18, wobei der Schritt (c) ferner folgende Schritte umfaßt:

(c3) Behandlung der konvexen Oberfläche der in Schritt (c2) vakuumgeformten Schicht mit einem Gleitmittel;

(c4) Mehrfaches Wiederholen der Schritte (c2) und (c3) zur Bildung einer mehrschichtigen pumpenden Membran; und

(c5) Verbinden der verschiedenen Schichten an ihren Rändern.

20. Verfahren nach einem der Ansprüche 13 bis 17, wobei der Schritt (c) folgende Schritte umfaßt:

(c1) Behandlung der Ränder der auf der konkav-

ven Form vakuumgeformten thermoplastischen Schicht mit einem klebenden Bindemittel; und

(c2) Vakuumformung einer dünnen Schicht aus thermoplastischen Polymeren auf die thermoplastische Schicht von Schritt (c1).

Revendications

1. Dispositif d'assistance ventriculaire comprenant:

— une enveloppe flexible allongée (12), de configuration sensiblement plate et à courbure douce de sorte qu'on peut l'implanter confortablement sous la peau ou à l'intérieur de la poitrine d'une malade, ladite enveloppe (12) comportant des moyens d'entrée (14), par lesquels le sang est admis dans l'enveloppe, et des moyens de sortie (16) par lesquels le sang est chassé de l'enveloppe;

— une membrane souple d'équilibrage (26) disposée à l'intérieur de l'enveloppe (12), cette membrane d'équilibrage (26) divisant une première partie de l'intérieur de l'enveloppe en une chambre à sang atriale (32) et une chambre d'équilibrage atriale (33), ladite chambre à sang atriale (32) étant en communication de fluide avec lesdits moyens d'entrée (14), et l'enveloppe comportant un ou plusieurs orifices (56) par lesquels un fluide peut entrer et sortir de ladite chambre d'équilibrage atriale (33); et

— une membrane de pompage (28) disposée à l'intérieur de l'enveloppe, cette membrane de pompage (28) divisant une deuxième partie de l'intérieur de l'enveloppe en une chambre à sang ventriculaire (34) et une chambre de pompage de fluide de commande (35), ladite membrane de pompage (28) étant déplaçable de manière forcée par ledit fluide de commande afin de chasser le sang de la chambre à sang ventriculaire à travers lesdits moyens de sortie,

caractérisé en ce que la membrane de pompage (28) est orientée sensiblement dans le même plan que la membrane d'équilibrage (26) et en ce que la chambre à sang atriale (32) et la chambre à sang ventriculaire (34) sont situées à des extrémités longitudinales opposées et du même côté de l'enveloppe (12).

2. Dispositif d'assistance ventriculaire suivant la revendication 1, caractérisé en ce que la membrane d'équilibrage (26) comprend une partie solide qui constitue un clapet à battant unidirectionnel (36) formé sur une extrémité de la membrane d'équilibrage pour commander la sortie de sang de la chambre à sang atriale.

3. Dispositif suivant la revendication 1 ou 2, caractérisé en ce qu'il comprend une valve unidirectionnelle (66) située dans les moyens de sortie (16) pour commander le passage du sang chassé de la chambre à sang ventriculaire par lesdits moyens de pompage.

4. Dispositif suivant l'une quelconque des revendications 1 à 3, caractérisé en ce que les surfaces intérieures de la chambre à sang atriale (32) et de la chambre à sang ventriculaire (34) sont sensiblement lisses et sans soudure et ont

une courbure progressive de façon à minimiser la formation de thrombus lorsque le sang circule à travers ces chambres.

5. Dispositif suivant l'une quelconque des revendications 2 à 4, caractérisé en ce que le clapet (36) est profilé de manière à se conformer au contour de la chambre à sang ventriculaire (34) lorsque ce clapet est fermé pour empêcher la circulation inverse de sang vers la chambre à sang atriale (32).

6. Dispositif suivant l'une quelconque des revendications 3 à 5, caractérisé en ce que la valve unidirectionnelle (66) placée dans les moyens de sortie (16) est séparable de ces derniers.

7. Dispositif suivant l'une quelconque des revendications 1 à 6, caractérisé en ce qu'il comprend en outre une pluralité de canaux de fluide (58) ménagés dans la surface intérieure de l'enveloppe (12) de façon à répartir le fluide de commande sous la membrane de pompage (28).

8. Dispositif suivant l'une quelconque des revendications 1 à 7, caractérisé en ce que la membrane d'équilibrage (26) et la membrane de pompage (28) comprennent une pluralité de couches en matière élastomère.

9. Dispositif suivant la revendication 8, caractérisé en ce que les couches sont liées les unes aux autres seulement à la périphérie desdites membranes.

10. Dispositif suivant la revendication 8 ou 9, caractérisé en ce que chacune des couches est en élastomère de type différent et en ce que les couches sont séparées par un lubrifiant.

11. Dispositif suivant l'une des revendications 1 à 10, caractérisé en ce qu'il comprend en outre une membrane mince et molle (52) sous la forme d'un péricarde artificiel lié à l'enveloppe de manière à enfermer lesdits orifices.

12. Dispositif suivant l'une des revendications 1 à 11, caractérisé en ce qu'il comprend en outre une pluralité de canaux de fluide (58) ménagés dans la surface intérieure de l'enveloppe (12) de manière à répartir le fluide de commande sous la membrane de pompage (28).

13. Procédé de fabrication d'un dispositif d'assistance ventriculaire, ce procédé comprenant les opérations de:

(a) formage sous vide d'une enveloppe (12) comportant des moyens d'entrée (14) par lesquels le sang est introduit dans l'enveloppe, des moyens de sortie (16) par lesquels le sang est chassé de l'enveloppe, et des moyens (18) par lesquels un fluide de commande est pompé dans et hors de l'enveloppe;

(b) formage sous vide d'une membrane d'équilibrage (26) qui comporte un clapet à battant solidaire unidirectionnel (36) pour commander la circulation du sang dans l'enveloppe;

(c) formage sous vide d'une membrane de pompage (28);

(d) jonction de la membrane d'équilibrage (26) à l'intérieur d'une première partie de l'enveloppe de manière à définir une chambre à sang atriale (32) et une chambre d'équilibrage atriale (33) qui sont séparées par une jonction étanche au fluide à

la périphérie de la membrane d'équilibrage (26); et

(e) jonction de la membrane de pompage (28) à l'intérieur d'une deuxième partie de l'enveloppe de manière à définir une chambre à sang ventriculaire (34) et une chambre de pompage de fluide de commande (35) qui sont séparées par une jonction étanche au fluide à la périphérie de la membrane de pompage;

de sorte que la membrane de pompage (28) est orientée dans le même plan que la membrane d'équilibrage (26) et de sorte que les chambres à sang atriale et ventriculaire (32; 34) sont situées aux extrémités longitudinales opposées et du même côté de l'enveloppe.

14. Procédé suivant la revendication 13, caractérisé en ce que l'opération (a) comprend les opérations de:

(a1) préparation d'un moule convexe ayant la même configuration que le dispositif d'assistance ventriculaire désiré;

(a2) formage sous vide d'une première couche de polymère thermoplastique sur ce moule;

(a3) inversion du moule; et

(a4) formage sous vide d'une deuxième couche de polymère thermoplastique sur ce moule.

15. Procédé suivant la revendication 13, caractérisé en ce que l'opération (a) comprend les opérations de:

(a1) préparation d'un moule convexe ayant la même configuration que le dispositif d'assistance ventriculaire désiré;

(a2) préparation d'un moule concave coulé à partir de la partie inférieure dudit moule convexe; et

(a3) formage sous vide d'une couche de polymère thermoplastique sur la partie supérieure dudit moule convexe et sur le moule concave.

16. Procédé suivant l'une quelconque des revendications 13 à 15, caractérisé en ce que l'opération (b) comprend les opérations de:

(b1) préparation d'un moule ayant la même configuration que la membrane d'équilibrage désirée; et

(b2) formage sous vide d'une couche mince de polymère thermoplastique sur ce moule.

17. Procédé suivant la revendication 16, caractérisé en ce que l'opération (b) comprend en outre les opérations de:

(b3) traitement de la surface convexe de la couche formée sous vide par l'opération (b2), avec un lubrifiant;

(b4) répétition des opérations (b2) et (b3) plusieurs fois, pour constituer une membrane d'équilibrage multicouche, et

(b5) liaison des couches multiples les unes aux autres le long de leurs bords.

18. Procédé suivant l'une quelconque des revendications 13 à 17, caractérisé en ce que l'opération (c) comprend les opérations de:

(c1) préparation d'un moule convexe ayant la même configuration que les membranes de pompage désirées; et

(c2) formage sous vide d'une couche mince de polymère thermoplastique sur ce moule.

19. Procédé suivant la revendication 18, caractérisé en ce que l'opération (c) comprend en outre les opérations de:

(c3) traitement de la surface convexe de la couche formée sous vide dans l'opération (c2), avec un lubrifiant;

(c4) répétition des opérations (c2) et (c3) plusieurs fois, pour constituer une membrane de pompage multicouche; et

(c5) liaison des couches multiples les unes aux

autres le long de leurs bords.

20. Procédé suivant l'une quelconque des revendications 13 à 17, caractérisé en ce que l'opération (c) comprend les opérations de:

(c1) traitement des bords de la couche thermoplastique formée sous vide sur ledit moule concave, avec un agent adhésif de liaison; et

(c2) formage sous vide d'une couche mince de polymère thermoplastique sur la couche thermoplastique de l'opération (c1).

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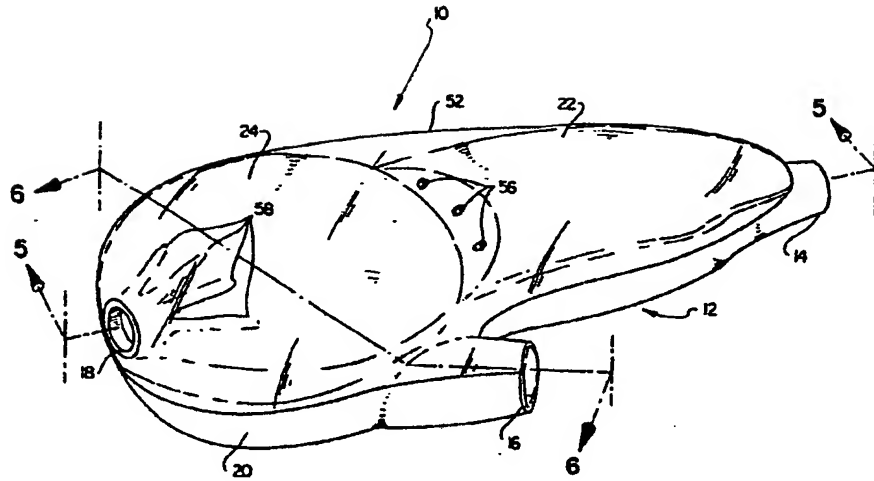


Fig. 1

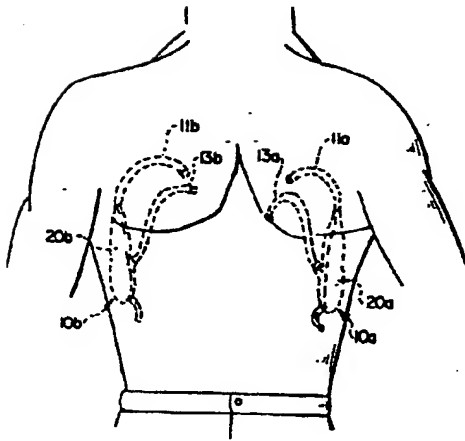


Fig. 2

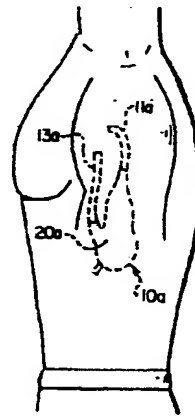
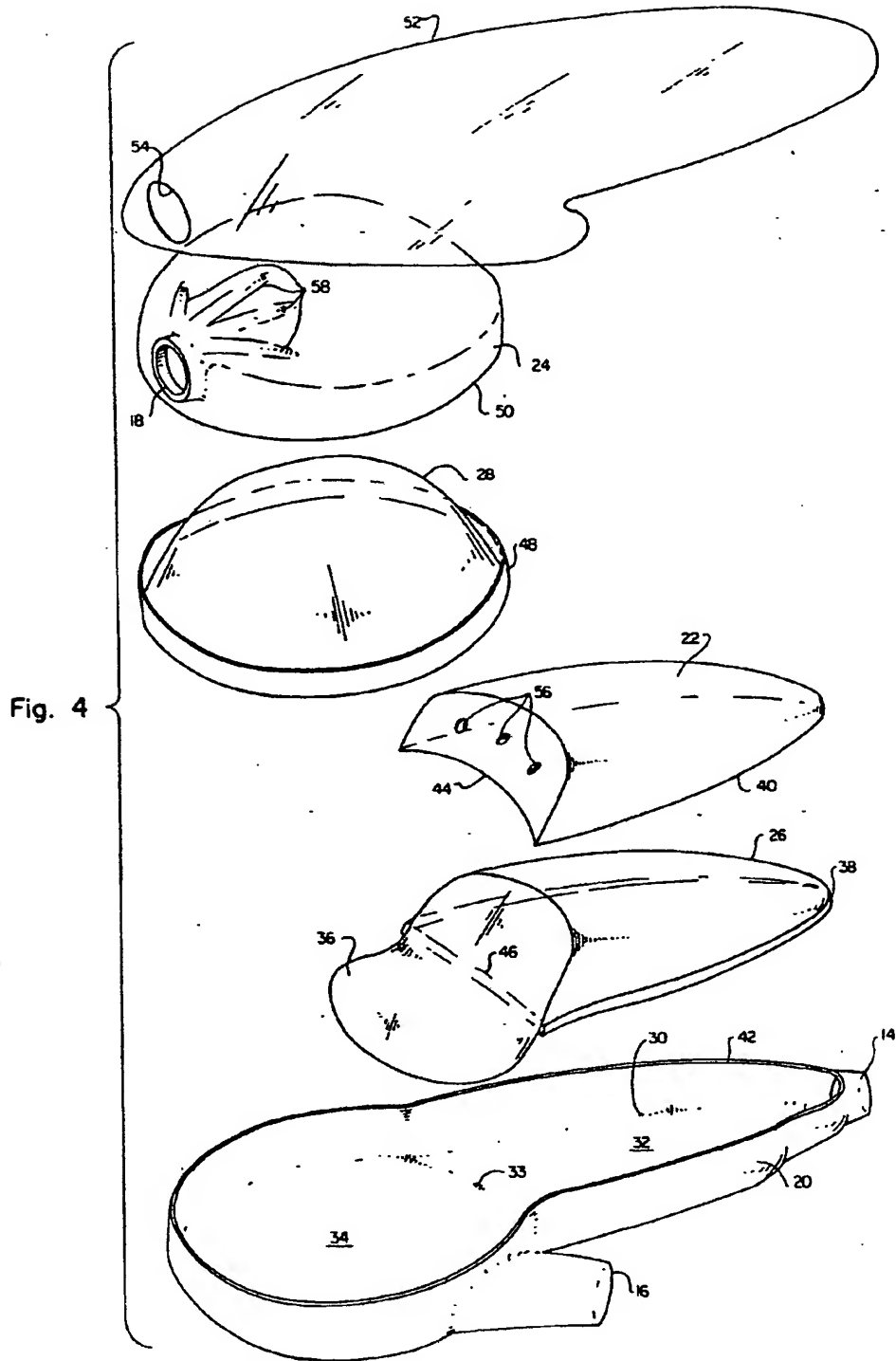


Fig. 3



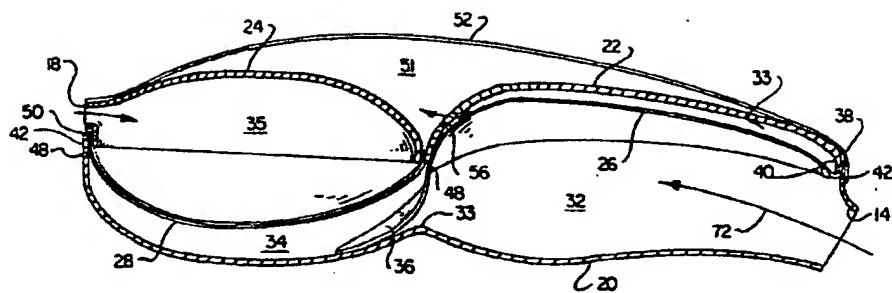


Fig. 5A

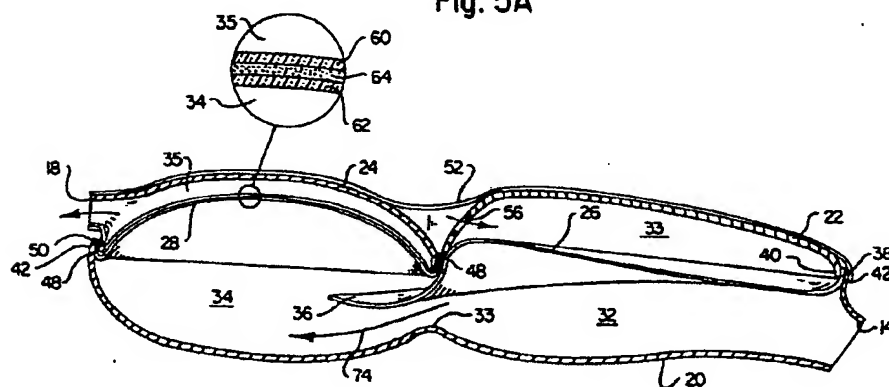


Fig. 5B

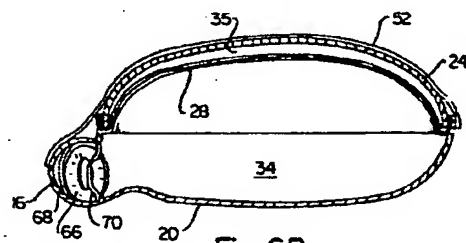


Fig. 6B

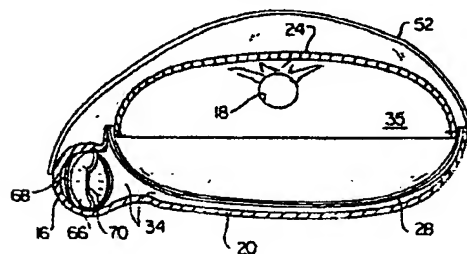


Fig. 6A

Fig. 7

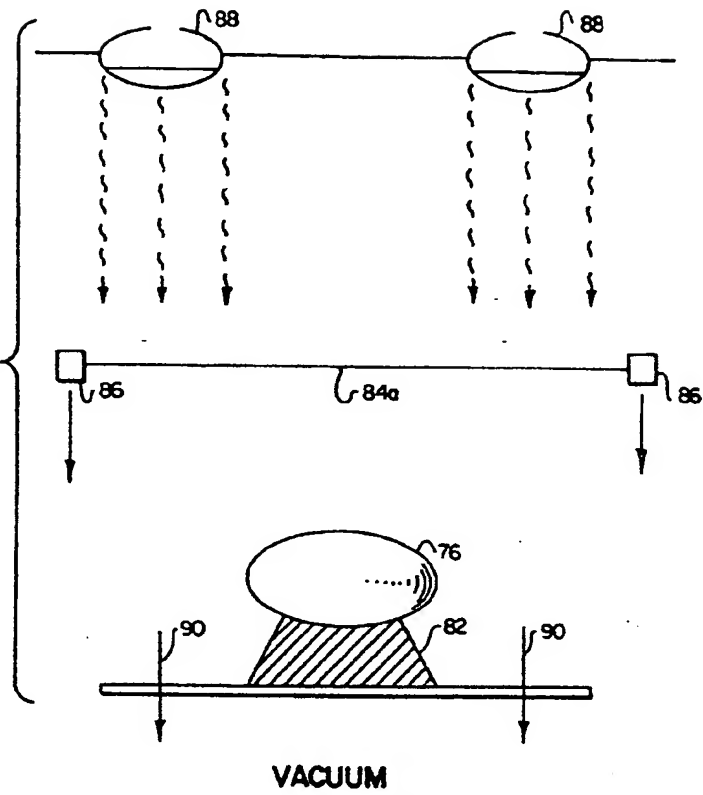
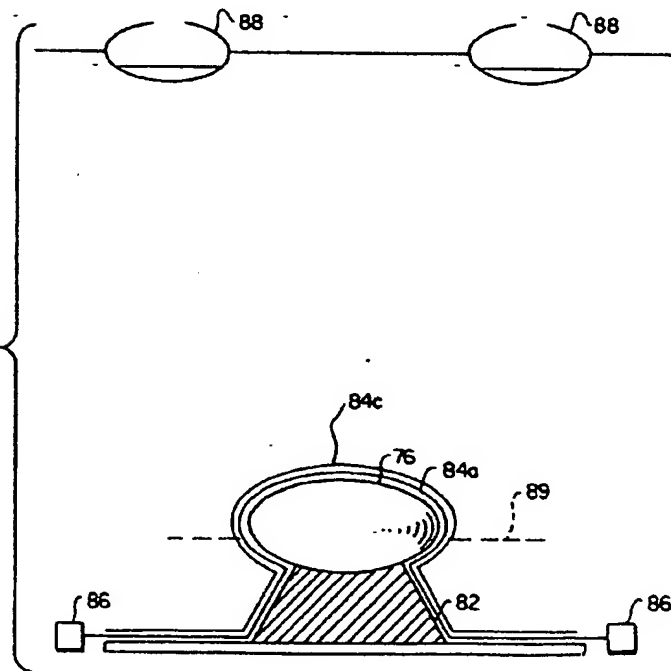
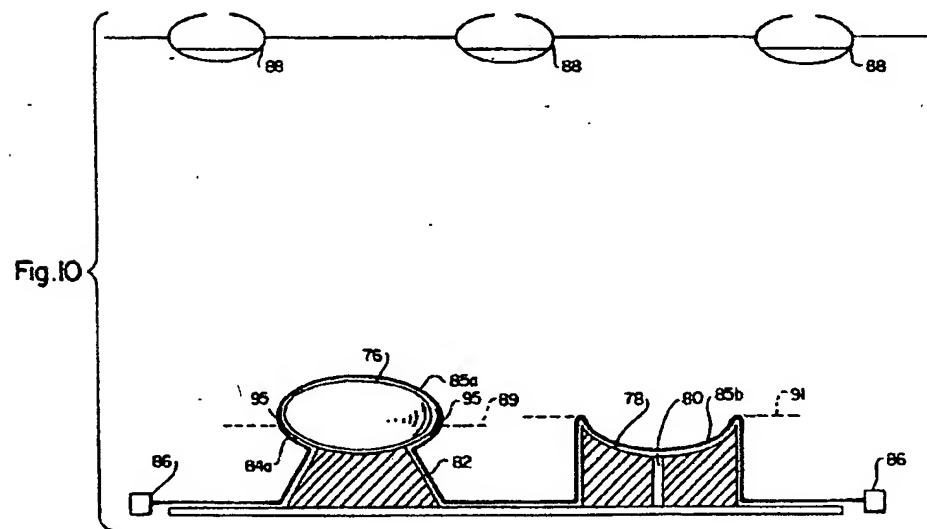
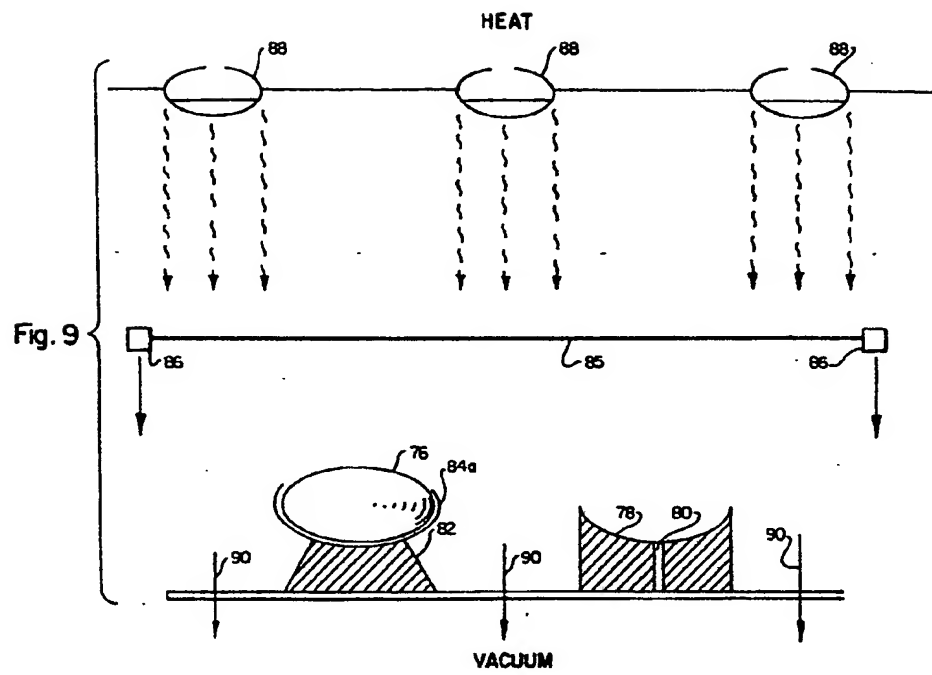
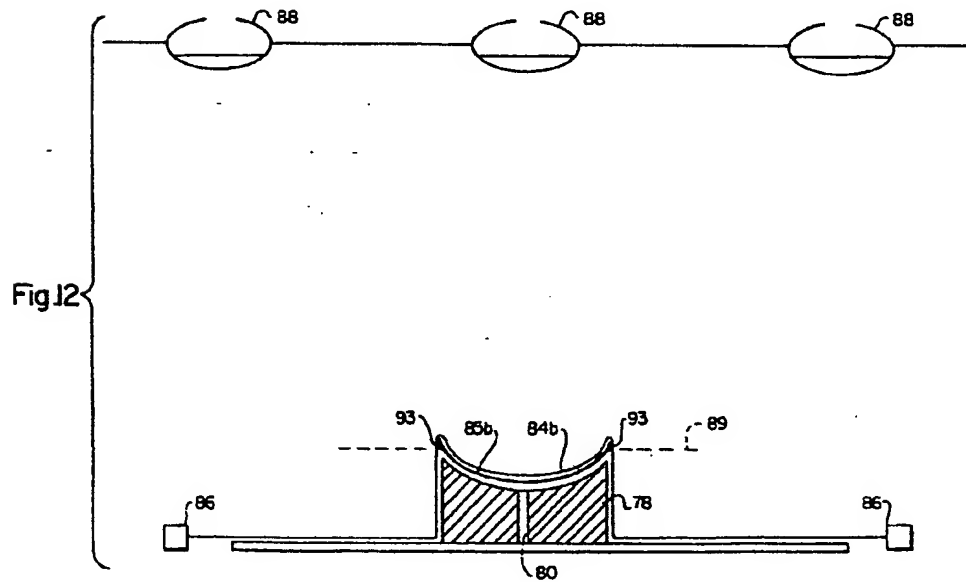
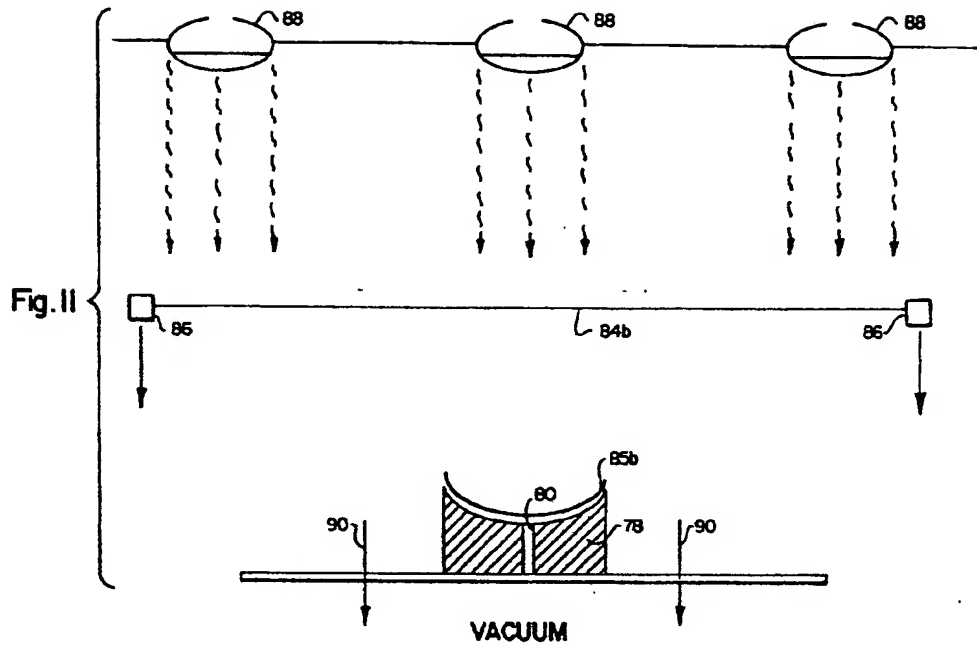


Fig. 8







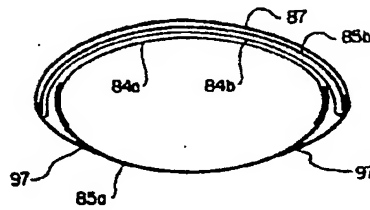
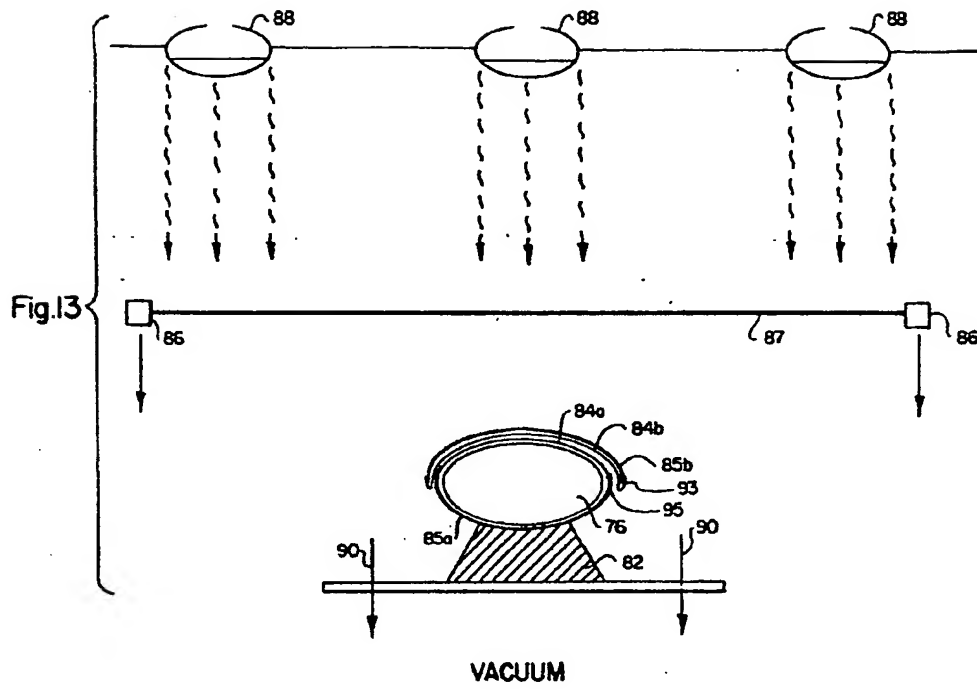


Fig. 14